Denali Therapeutics Announces First Clinical Trial Application, Key Collaborations And $130M Series B

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SOUTH SAN FRANCISCO, Calif., Aug. 25, 2016 /PRNewswire-USNewswire/ -- Denali Therapeutics Inc. ("Denali") today announced several critical milestones in the company's growth, including its first Clinical Trial Application ("CTA") to initiate a Phase 1 trial, previously undisclosed collaborations and licensing deals, and a $130 million Series B equity financing.

"We are pleased to share some of the significant progress we have made in building out Denali's systematic and novel approaches and capabilities to defeat degeneration," said Ryan Watts, PhD, CEO. "We continue to progress toward our ultimate goal of helping patients who suffer from debilitating neurodegenerative disease," said Dr. Watts.

Denali is developing a diversified portfolio of therapeutics, based on scientific insights into the genetic causes and biological processes underlying neurodegenerative disease. The company has selected four specific pathways that are implicated as triggers or effectors of neurodegeneration: degenogenes (genes that cause neurodegenerative disease when mutated), defective intracellular trafficking, glial dysfunction and axon degeneration. Denali is pursuing a rigorous biomarker-driven development strategy for each of these pathways.

Clinical Trial Application

On August 22, Denali filed a CTA in Europe to initiate a Phase 1 clinical trial for a small molecule RIP1 inhibitor with central nervous system (CNS) penetrant properties. RIP1 is a kinase that regulates inflammatory signaling and can affect glial dysfunction in the brain. Pending CTA approval, Denali will proceed with a single center study in healthy volunteers to assess safety, tolerability, and pharmacokinetics. Data from this trial will inform the design of future studies in patients suffering from ALS (Amyotrophic Lateral Sclerosis) and Alzheimer's disease.

"Mounting genetic evidence points to glial dysfunction as an accelerator of neurodegeneration, and we believe that advancing our RIP1 inhibitor into human clinical testing is a significant step in bringing forward a novel mechanism to combat ALS and Alzheimer's disease," said Dr. Carole Ho, Chief Medical Officer.

Collaborations and Licensing Deals

Denali has also completed a number of business transactions to complement and accelerate internal research and development. "We are excited to work with world-class corporations and academic institutions to explore and develop the most promising approaches," said Dr. Alex Schuth, COO. "Partnerships are central to Denali's strategy and we continue to seek collaborations to discover and develop effective medicines for patients," said Dr. Schuth.

Today, Denali disclosed the following transactions:

- Acquisition of San Diego-based Incro Pharmaceuticals for access to its RIP1 inhibitor program, which originated from a license and collaboration agreement with Harvard University
- License agreement with Genentech, a member of the Roche group, for exclusive global rights to develop and commercialize LRRK2 inhibitors for the treatment of Parkinson's disease
- Research collaboration and exclusive license agreement with Washington University School of Medicine in St. Louis for the development and commercialization of antibodies targeting ApoE, a neurodegeneration-causing protein and genetic risk factor for Alzheimer's disease
- Research collaboration and option agreement with UK-based F-star in support of the development of a proprietary platform technology to deliver therapeutics across the blood-brain barrier
- Research collaboration and option agreement with Blaze Bioscience for research on and discovery of novel blood-brain-barrier crossing therapeutics at the Fred Hutchinson Cancer Research Center

Other strategic partnerships include collaborations with ALS Therapy Development Institute (ALS TDI), Aptuit, Evotec, Massachusetts General Hospital, the Michael J. Fox Foundation, PatientsLikeMe and the University of California San Diego School of Medicine.

Equity Financing

In order to fund its therapeutic pipeline and proprietary blood-brain-barrier delivery technology platform, Denali raised an additional $130 million in preferred equity capital through a Series B financing in June 2016. All of Denali's founding investors participated in this second financing round, which was led by Baillie Gifford, a UK-based mutual fund and included several new and large institutional investors.

ABOUT DENALI THERAPEUTICS INC.

Denali Therapeutics Inc. is a privately held biotechnology company focused on the discovery and development of therapies for patients with neurodegenerative disease, including Alzheimer's disease, Parkinson's disease, ALS and others. Located in South San Francisco, Denali was founded by Drs. Marc Tessier-Lavigne, Ryan Watts, Alex Schuth and investors who share the vision that recent scientific insights in genetics, biology and translational medicine offer an unprecedented opportunity to discover and develop effective medicines for neurodegenerative disease. Denali is rigorously pursuing a science-driven approach to translational medicine and clinical development. Founding investors include ARCH Venture Partners, F-Prime Biosciences, Flagship Ventures and the Alaska Permanent Fund. To learn more, visit our website: www.denalitherapeutics.com .